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| **Application No.** | : | **2,348,756** |
| **Owner** | : | RESISTENTIA PHARMACEUTICALS AB |
| **Title** | : | **ENHANCED VACCINES COMPRISING SELF AND NON-SELF IGE PORTIONS OR DIMERIC ANTIGENS** |
| **Classification** | : | A61K-39/00 |
| **Your File No.** | : | **8978-56 JHW:jm** |
| **Examiner** | : | X. Ma |

IN ACCORDANCE WITH SUBSECTION 30(2) OF THE PATENT RULES, YOU ARE HEREBY NOTIFIED OF A REQUISITION BY THE EXAMINER. IN ORDER TO AVOID ABANDONMENT UNDER PARAGRAPH 73(1)(A) OF THE PATENT ACT, A WRITTEN REPLY MUST BE RECEIVED WITHIN 6 MONTHS AFTER THE ABOVE DATE.

This application has been examined taking into account applicant's correspondence dated January 24, 2003.

The number of claims in this application is 71.

The claims are directed to a plurality of alleged inventions as follows:

**Group A** - Claims 1-22 are directed to an immunogenic polypeptide comprising a self IgE portion and a non-self IgE portion and its corresponding nucleic acids, host cells, dimer, and vaccine comprising said polypeptide, and methods of making said polypeptide;

**Group B** - Claims 23-36 and 40-43 are directed to a vaccine complex comprising a first and a second polypeptide, each of said first and second polypeptides containing at least two similar amino acid sequences having at least five amino acid residues in length; and

**Group C** - Claims 37–39 (partially) and 44-71 are directed to a vaccine complex comprising a first, a second and, optionally, a third polypeptide, at least one of said polypeptide having cytokine activity.

The claims must be limited to one invention only as set out in Section 36 of the Patent Act.

A search of the prior art has revealed the following:

References Applied:

Canadian Applications

| | | |
|---|---|---|
| 2,117,193 | April 1, 1993 | Hellman LT |
| 2,320,960 | Filed February 10, 1999, laid open August 19, 1999, with a priority date of February 11, 1998 | Punnonen J et al |

PCT Application

| | | |
|---|---|---|
| WO 97/22699 | June 26, 1997 | Chatterjee M et al |

Hellman discloses an immunogenic polypeptide, comprising an IgE portion from an animal to be vaccinated and an IgE portion from a different animal, wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in said animal being vaccinated. Hellman also discloses a nucleic acid molecule encoding said immunogenic polypeptide, a host cell comprising said nucleic acid, a vaccine comprising said immunogenic polypeptide, and an immunogenic dimer comprising two of said immunogenic polypeptide that is capable of dimerizing together. Hellman further discloses a method for making a nucleic acid that encodes an immunogenic polypeptide effective to induce an anti-self IgE response in a mammal, comprising selecting a first nucleic acid sequence which encodes at least a portion of an IgE molecule present within said mammal, selecting a second nucleic acid sequence which encodes at least a portion of an IgE molecule not present in said mammal, and combining said first and second nucleic acid sequences to form said nucleic acid molecule.

Punnonen et al disclose a vaccine complex comprising a first and second polypeptide, wherein said first polypeptide is a polypeptide having interferon alpha or beta activity. Said complex can induce an immune response against said second polypeptide.

Chatterjee et al disclose a vaccine complex comprising a first and a second polypeptides connected to form said complex, wherein each of said first and second polypeptides contains at least two similar amino acid sequences having at least five amino acid residues in length. Said complex may further comprise a third polypeptide, and at least one of said polypeptide has a cytokine activity.

The examiner has identified the following defects in the application:

Claims 1, 14, 16, 18, 19, 21 and 22 do not comply with Paragraph 28.2(1)(a) of the Patent Act. The subject matter defined by these claims was disclosed by Hellman more than one year before the filing date of the present patent application. The immunogenic polypeptide, nucleic acid molecule, host cell, vaccine, immunogenic dimer and method disclosed by Hellman anticipate the claimed immunogenic polypeptide, nucleic acid molecule, host cell, vaccine, dimer and methods.

Claims 23, 44 and 56 do not comply with Paragraph 28.2(1)(b) of the Patent Act. Chatterjee et al disclosed the claimed subject matter before the claim date. The complex disclosed by Chaterjee et al anticipates the claimed vaccine complexes.

Claim 66 does not comply with Paragraph 28.2(1)(d) of the Patent Act. Before the claim date, the subject matter was disclosed in co-pending application to Punnonen J et al, which has an earlier priority date than the claim date of the present application. The vaccine complex disclosed by Punnonen et al anticipates the claimed complex.

Claims 1, 14, 16, 18, 19, 21 and 22 are indefinite and do not comply with Subsection 27(4) of the Patent Act. The terms "a self IgE portion" and "a non-self IgE portion" in the claimed Immunogenic polypeptide (claim 1), nucleic acid molecule (claim 14), host cell (claim 16), soluble immunogenic dimer (claim 18), vaccine (claim 19), and methods (claims 21 and 22) must be explicitly and distinctly defined by naming a specific portion in an IgE molecule or by reciting the amino acid sequence of said portion in the claims. Further, the terms "self IgE portion" and "non-self IgE portion" are confusing. It is not clear whether said "self IgE portion" refers to an IgE from the same animal to be vaccinated or from an animal of same species. It is not clear whether said "non-self IgE portion" refers to an IgE from a different animal of the same species or from an animal of a different species. The term "non-self IgE portion" may also refer to any protein which is not a self IgE.

Claim 16 is ambiguous and does not comply with Subsection 27(4) of the Patent Act. Claim 16 should clearly state the claimed host cell is an <u>isolated</u> host cell, in order to differentiate from a host cell comprised in an animal.

Claims 23, 44 and 56 are indefinite and do not comply with Subsection 27(4) of the Patent Act. The claimed immune complexes are not clearly and specifically defined in unambiguous terms. The claimed complex must be explicitly defined by reciting the amino acid sequence of the polypeptides, or by naming a specific polypeptide, comprised in said complex.

Under Section 29 of the Patent Rules, applicant is requisitioned to give the latest status of the corresponding United States and European Patent Office applications and the patent numbers, additional art cited, and any conflict, opposition, re-examination or similar proceeding encountered, subsequent to applicant's correspondence of January 24, 2003.

In view of the foregoing defects, the applicant is requisitioned to amend the application in order to comply with the Patent Act and the Patent Rules or to provide arguments as to why the application does comply.

X. Ma
Patent Examiner
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